

WDN:SLR 5/9/06 516307.doc  
PATENT

Attorney Reference Number 6907-55924-01  
Application Number 09/729,658

### Remarks

Claims 1, 2, 4, 23-26, 60-63, 65-68 and 72-77 are pending. By this amendment, claim 78 is added and claims 60-62, 66-68, 72, 75, and 77 would be cancelled without prejudice to prosecution in a future application. Therefore, claims 1, 2, 4, 23-26, 63, 65, 73-74, 76, and 78 would be pending upon entry of this amendment.

Support for the amendments and new claim can be found throughout the specification, for example:

Claim 1: page 8, lines 11 and 15; page 12, lines 18-31; page 17, lines 12-15; page 50, line 27; page 54, lines 15-17.

Claims 24-25: amended to remove unnecessary language.

Claims 73-74: amended due to the cancellation of claim 72 and to correct antecedent basis in claim 74.

Claim 76: amended due to the cancellation of claim 75.

Claim 78: page 21, lines 21-25

No new matter is added by these amendments, and no amendments were made to distinguish prior art.

### ***Relationship of Pascal Schneider to Licensee***

Applicants note that Pascal Schneider, whose declarations dated April 24, 2005 and June 14, 2005 were previously submitted to the USPTO for this application, is a paid consultant for a licensee of this invention.

### ***Claim objections***

Claims 24-25 are objected to because they recite that a protein encodes a polypeptide. Claims 24-25 are amended to remove the phrase "and which encodes a polypeptide."

Claim 72 was objected to as a substantial duplicate of claim 2. Therefore, claim 72 is cancelled. It appears claim 75 is a substantial duplicate of claim 4, and therefore claim 75 is cancelled.

In view of these amendments, Applicants request that the claim objections be withdrawn.

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**35 U.S.C. § 112, first paragraph**

Claims 1-4, 22-26, 41, 42, 59-69, and 72-77 are rejected under 35 U.S.C. § 112, first paragraph, on the grounds that these claims do not comply with the enablement requirement. Although Applicants respectfully disagree, claim 1 is amended to clarify that the subject is a newborn subject and to clarify that the EDA1-II protein comprises at least 95% sequence identity to amino acids 239-391 of SEQ ID NO: 2. As stated on page 3 of the Office action, the specification is enabled for the treatment of newborns suffering from XLHED or HED, and page 9 of the Office action states that Applicants have demonstrated the operability of a sequence comprising amino acids 239-391 of SEQ ID NO: 2. Because it is generally the position of the USPTO that it would not require undue experimentation to generate sequences having at least 95% sequence identity to a given sequence, claims that include language of at least 95% sequence identity in combination with functional language are allowable in the absence of data with such variants.

As Applicants have shown that administration of an EDA1-II fragment can promote hair follicle development and sweat gland development in a newborn animal model of ectodermal dysplasia, using the methods disclosed in the application, the pending claims are fully enabled.

In view of these amendments, and the Rule 132 Declarations previously presented, Applicants request that the 35 U.S.C. § 112, first paragraph rejection be withdrawn.

It is believed that the amendments place this application in condition for allowance, and therefore request that the amendment be entered. If there are any minor issues that need to be resolved prior to issuing a Notice of Allowance, the Examiner is invited to telephone the undersigned.

Respectfully submitted,

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